U.S. Serial No. 10/794,751 Filing Date: February 27, 2004

### REMARKS/ARGUMENTS

# Response to Restriction Requirement

The Office has required election of one invention under 35 U.S.C. §121 between the following groups:

I: Claims 1-17, drawn to an MRI contrast agent comprising a heterocyclic chelator (e.g., DOTA) and a therapeutic blocking moiety; and

II: Claims 1-11, drawn to an MRI contrast agent comprising an acyclic chelator (e.g., DTPA) and a therapeutic blocking moiety.

Applicants hereby elect the invention of Group I, Claims 1-17, with traverse.

# Response to Election of Species Requirement

The Office also requires the election of a single species with all variables defined. Accordingly, Applicants elect the following:

Therapeutic blocking moiety: doxorubcin;

Cleavage site: carbohydrate; and

Cleavage enzyme: carbohydrase.

Applicants respectfully submit that Claims 10 and 17 read upon this election and that Claims 1, 2, 3, 4, and 11-15 are generic.

#### Remarks Against Restriction Requirement

A restriction is proper only when two conditions are met: (1) the inventions are independent or distinct as claimed, and (2) the search and examination of the entire application places a serious burden on the examiner. M.P.E.P. § 803. Here, neither the "independent" nor "distinct" criteria are met as between the claims. Furthermore, search and examination of all claims is coextensive in nature. Therefore, restriction is improper.

M.P.E.P. § 802.01(I) further states that "[t]he term 'independent' (i.e., not dependent) means that there is no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect." The claimed methods of using the MRI contrast agents do not fit this definition.

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In particular, the inventions depend on the same operation, i.e., the use of either a macrocyclic chelator (e.g., DOTA) or an acyclic chelator (e.g., DTPA) as part of a MRI contrast agents to produce a magnetic resonance image of a cell, tissue, or patient and elicit a therapeutic effect. Therefore, they do not fit the M.P.E.P. § 802.01(I) "unconnected in operation" element of independent inventions.

Furthermore, M.P.E.P. § 809 recognizes that a "linking claim" will act to prevent final restriction of two or more claims that may be "otherwise divisible." M.P.E.P. § 809 defines "linking claims" by stating that:

Linking claims and the inventions they link together are usually either all directed to products or ... processes. ... The most common types of linking claims which, if allowable, act to prevent restriction between inventions that can otherwise be shown to be divisible, are (A) genus claims linking species claims ... (emphasis added).

Here, Claim 1 is a linking claim that is directed to a method of using a MRI agent that includes administering the MRI agent that includes a chelator, a paramagnetic metal ion, and a therapeutic blocking moiety, cleaving a cleavage site that releases the therapeutic blocking moiety, thereby producing an MRI image and eliciting a therapeutic effect. Claim 2 is directed to either a macrocyclic (DOTA) or an acyclic (DPTA) variation of the chelator as recited in claim 1. Therefore, the claims recite a reasonable number of species to be linked by generic claim 1. The present claims do not present a number of widely diverging species; rather, they present a limited number of particular chelators. Because the species of claim 2 are linked by collectively requiring all of the limitations of generic claim 1, and are reasonable in number, restriction is improper under M.P.E.P. § 809.

Because the claimed variants are connected in design, operation, and effect, they do not fit the requirements for independent inventions. The Applicants therefore respectfully request withdrawal of the restriction requirement and examination on the merits of the application with respect to all pending claims.

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#### **CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-442-1000.

Respectfully submitted,

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